

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
11 November 2004 (11.11.2004)

PCT

(10) International Publication Number
WO 2004/096067 A2

(51) International Patent Classification⁷: **A61B 17/72**
(21) International Application Number:
PCT/GB2004/001867
(22) International Filing Date: 29 April 2004 (29.04.2004)
(25) Filing Language: English
(26) Publication Language: English
(30) Priority Data:
0309695.5 29 April 2003 (29.04.2003) GB

(71) Applicant (for all designated States except US):
GRAMPIAN UNIVERSITY HOSPITALS NHS TRUST [GB/GB]; Foresterhill House, Ashgrove Road West, Aberdeen AB25 2ZB (GB).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **JOHNSTONE, Alan, John** [GB/GB]; The Elms, 7 North Deeside Road, Bieldside, Aberdeen AB15 9AD (GB).

(74) Agent: **MURGITROYD & COMPANY**; 165-169 Scotland Street, Glasgow G5 8PL (GB).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

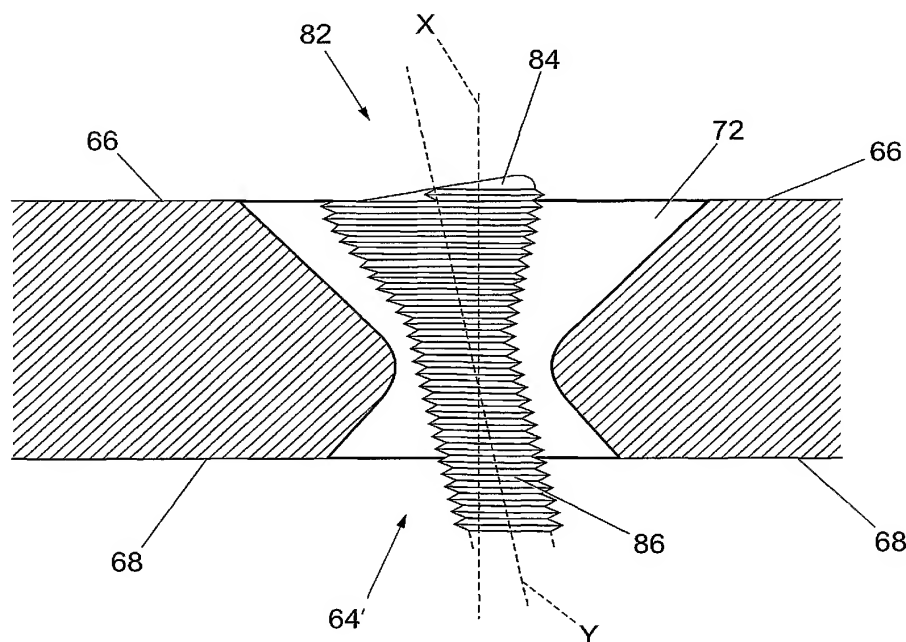
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

[Continued on next page]

(54) Title: APPARATUS



(57) Abstract: A bone fixture apparatus such as plate or an intramedullary nail is disclosed, having a plug or other form of insert that engages screws passing through the nail or plate etc. The provision of the pliable insert allows the screw to be driven through the plate etc at a number of different angles. The application also concerns a pliable insert suitable for use with the plate or nail.

WO 2004/096067 A2



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

1 "Apparatus"

2

3 This invention relates to apparatus for use in
4 supporting a fractured bone.

5

6 It is known to support fractures in bones by rigid
7 bone fixture implants, common examples of which are
8 bone plates (commonly known as interlocking plates)
9 and intra-medullary (IM) nails.

10

11 IM nails are inserted into the medullary canal of
12 the long bone, and are held in place by screws or
13 other bone fasteners such as bolts or pins that are
14 driven laterally through the bone, typically at each
15 end of the nail. The screws etc also pass through
16 pre-drilled holes in the nail, thereby reducing or
17 preventing movement of the nail while the fracture
18 is healing. Holes must be bored through the bone in
19 order to insert the screws, and these must be
20 aligned with the pre-drilled holes in the ends of
21 the nail.

22

1 In order to drill the holes accurately through the
2 bone, a jig is commonly employed. The jig is
3 attached to the protruding end of the nail after
4 insertion of the nail into the medullary canal, and
5 typically extends parallel to the nail. The jig has
6 pre-drilled holes that align with the holes in the
7 nail when the jig and the nail are properly
8 attached.

9
10 Interlocking bone plates are normally attached to
11 the exterior surface of bones using similar bone
12 fasteners such as bolts or screws. Like the IM
13 nail, the plate is arranged to span fractures and
14 the bone fasteners penetrate solid bone on opposing
15 sides of the fracture(s).

16
17 According to the present invention there is provided
18 a bone fixture apparatus having a pliable material
19 for engaging a fixing device.

20
21 The bone fixture apparatus can be attached to the
22 outer or the inner surface of the bone. Typically,
23 the bone fixture apparatus comprises an intra-
24 medullary nail. Alternatively, the bone fixture
25 apparatus comprises a bone plate (internal or
26 external). Alternatively, the bone fixture
27 apparatus comprises a fracture brace.

28
29 Typically, the pliable material is capable of
30 plastic and/or elastic deformation, and can
31 typically be a coating or insert. The pliable
32 material is typically softer than the material of

1 the bone fixture apparatus, and has a lower Young's
2 modulus. The pliable material is preferably soft
3 enough to drill, mill or cut peroperatively,
4 typically under the influence of materials that are
5 harder than the pliable material. Typically such
6 harder materials are used for the fixing device
7 which is driven into the pliable material.

8
9 Optionally, the pliable material is a metal or a
10 polymer. In certain embodiments the pliable
11 material can be biodegradable. Biodegradable
12 variants are useful as the plate or nail typically
13 needs to be firmly attached to the bone without
14 allowing any movement only in the initial phase of
15 the fracture, so that it can take the loading
16 normally applied to the fractured area of bone
17 arising from everyday use. After the fracture has
18 healed, the implant is redundant and no longer needs
19 to bear any load. In some cases, the implant can be
20 left in place permanently, but in other cases, the
21 implant can be removed from the bone, and
22 biodegradable inserts of the pliable material can
23 assist in such removal, as by the time the bone has
24 healed, the pliable material will have been eroded,
25 and the fixings can be more easily removed.

26

27 Biodegradable versions of the insert also lend
28 themselves very well to use with bone plates having
29 dynamization slots, as the screw can be driven
30 through the dynamization slot filled with the
31 pliable insert, and the degradation of the insert
32 over the succeeding weeks or months will then free

1 the screw to move axially in the slot once the
2 initial healing has progressed to a suitable phase
3 where this movement is desirable, but retaining a
4 secure fixing of the screw, plate and bone when this
5 is necessary in the initial phase before healing of
6 the bone fracture.

7
8 The pliable material can be a non-metallic material
9 such as plastics material or an expanded carbon
10 complex. A further possibility is that the pliable
11 material is a naturally occurring (and preferably
12 bioabsorbable) material such as a collagen or
13 polypeptide construct.

14
15 The apparatus may have a hole to receive the fixing
16 device, and the pliable material may preferably be
17 located at or in the hole. Preferably, the pliable
18 material is positioned e.g. bonded on a surface
19 (typically the internal surfaces of an aperture or
20 bore) of at least a part of the bone fixture
21 apparatus. Preferably, some pliable material is
22 disposed in the region(s) of the bone fixture
23 apparatus around or within the hole(s). In some
24 embodiments in the form of hollow nails etc, the
25 pliable material can be inserted into a central
26 canal of the nail.

27
28 In some embodiments, the pliable material is
29 settable so that it changes phase (e.g. from paste,
30 gel or liquid to a solid) on the application of
31 pressure or heat, when exposed to a chemical

1 catalyst, or after an interval of time. Optionally,
2 the settable material is a glue or a paste.

3
4 The pliable material is optionally self-expanding.
5 Optionally, the pliable material changes phase, e.g.
6 from liquid to solid when it expands.

7
8 Optionally, the bone fixture apparatus has
9 predrilled holes to receive fixings. The holes can
10 be on different planes, and can be lateral holes or
11 in other planes. The holes can be filled or lined
12 with pliable material. Optionally, screws or other
13 bone fixings are inserted into the pliable material
14 to form holes through the pliable material. In such
15 cases the bone fixture apparatus can have a window
16 through which the pliable material is exposed to the
17 fixing, and through which the screw etc can be
18 inserted. In certain cases the pliable material can
19 have a pilot hole pre-drilled therein to receive the
20 bone fixing.

21
22 Preferably, the fixing device is a screw or a bolt.
23 Threaded fixings are preferred, but non-threaded
24 fixings such as pins etc can be used. Preferably,
25 the fixing device is longer than the diameter of the
26 apparatus.

27
28 In some nails formed as a rolled tube, each hole has
29 a circumferentially opposite hole. Each hole (or
30 pair of opposite holes) can typically receive the
31 fixing device. Potentially, the pair of opposite
32 holes could form the ends of a generally cylindrical

1 passage through a solid nail. The entire passage
2 could be filled with pliable material, or
3 alternatively the walls of the passage could be at
4 least partially lined with pliable material. In
5 some embodiments the pliable material can comprise
6 at least one ring (preferably two rings) of e.g.
7 plastics material such as Nylon(TM) on the inner
8 diameter of (or within) at least one of the holes
9 (preferably each end of each hole has a respective
10 ring).

11
12 Optionally, the pliable material extends down the
13 full length of cannulated nails, although it is only
14 necessary for the pliable material to be located
15 where the fixing devices engage the bone fixture
16 apparatus; thus the pliable material and/or the
17 holes to engage the bone fixings could be anywhere
18 on the apparatus.

19
20 Optionally, the holes have parallel sides, but in
21 certain embodiments, the sides of the holes are
22 tapered. Bi-directionally tapered embodiments,
23 where the sides of the holes taper inwardly from
24 both the upper and lower surfaces of the bone fixing
25 apparatus to an apex, can be advantageous, as the
26 narrower width of the hole at the apex can serve to
27 hold the pliable material in position, without the
28 need for an adhesive. The apex of the hole is
29 typically located just below the centre point of the
30 hole axis. The embodiments having bi-directional
31 tapering are typically used with a solid insert of

1 pliable material which fills, or nearly fills the
2 hole.

3
4 Optionally, the pliable material is in the form of
5 an insert which has a compressible portion. This
6 kind of insert is especially useful for use with
7 holes having a narrow portion. The compressible
8 portion can be compressed to fit through the narrow
9 portion of the hole. The compressible portion may
10 have legs divided by elongate slits. The slits are
11 typically wedge-shaped, and allow for the legs to be
12 pushed together to reduce the diameter of the
13 compressible portion. For example, before
14 compression, the legs may form part of a frusto-
15 conical portion of the insert; thus the legs have a
16 partially radial extent. On compression, the legs
17 can be squeezed into a cylindrical shape to fit
18 through the narrow portion of the hole. It is
19 useful if the compressible portion is formed from a
20 resilient material, so that when the legs have
21 passed through the narrow portion of the hole, they
22 extend radially outwards again to hold the insert in
23 the hole.

24
25 Other embodiments of bone fixing apparatus have
26 tapered frusto-conical holes. These may be used
27 with inserts which fill the holes, or alternatively,
28 the hole walls may be lined with the pliable
29 material.

30
31 The holes in the bone fixing apparatus may be screw-
32 threaded and the pliable material may be in the form

1 of an insert having corresponding threads;
2 alternatively, threads may be formed in the insert
3 on screwing the insert into the threaded holes.

4

5 Optionally, the nail can be hollow and the entire
6 cross-section of the nail is filled with the pliable
7 material, at least in the areas where the screws
8 will engage the nail, e.g. at the ends.

9 Alternatively, the bone fixture apparatus can be
10 solid and the pliable material can comprise a hollow
11 sleeve or ring(s), or a solid plug inside a passage
12 through the bone fixture apparatus adapted to
13 receive the fixing screws. Another possibility is
14 that the pliable material lines the inside surface
15 of a hollow bone fixture apparatus.

16

17 According to a further aspect of the present
18 invention, there is provided a method of supporting
19 a fractured bone, the method comprising the steps
20 of: attaching a bone fixture apparatus to the bone
21 and engaging at least one fixing device with the
22 bone, wherein the bone fixture apparatus is provided
23 with a pliable material and the fixing device is
24 engaged with the pliable material.

25

26 The bone fixture apparatus may comprise an intra-
27 medullary nail, and the method optionally includes
28 the step of inserting the intra-medullary nail into
29 the medullary cavity of the bone. Alternatively,
30 the bone fixture apparatus may comprise a bone
31 plate.

32

1 Preferably, the apparatus spans one or more
2 fractures in the bone, and the screws are driven
3 into the bone fixture apparatus on opposing sides of
4 the fracture(s).

5

6 The pliable material is typically attached to a part
7 of the bone fixture apparatus.

8

9 The fixing device may optionally be inserted through
10 at least one hole in the bone fixture apparatus; the
11 hole is typically at least lined and optionally
12 filled with pliable material. The pliable material
13 may be inserted into the hole either before or after
14 the bone fixture apparatus is attached to the bone.

15

16 A simple option is to fill the holes in the bone
17 fixture apparatus with pliable material. A simple
18 ring of plastic material around the inside of each
19 hole would be sufficient, and in such cases the
20 inner diameter of the ring is preferably less than
21 the diameter of the shank of the screw. Another
22 possibility is to insert one or more sleeves or
23 cylinders of pliable material to span the gap(s)
24 between holes in opposite sides of a hollow bone
25 fixture apparatus and is supported by the holes.

26

27 Typically, the pliable material acts to minimize
28 movement of the screw with respect to the bone
29 fixture apparatus.

30

31 Typically, inserting a screw displaces some of the
32 pliable material, which expands against a surface of

1 the bone fixture apparatus. This expansion force
2 helps to hold the screw stationary with respect to
3 the bone fixture apparatus. In such examples, the
4 pliable material is typically contained within a
5 containment area in the bone fixture apparatus, so
6 that when the pliable material expands it pushes
7 against the walls of the containment area and
8 increases the grip between the bone fixture
9 apparatus and the screw. In certain embodiments the
10 material can be self-expanding, and this can
11 increase the grip of the screw on the bone fixture
12 apparatus. In other embodiments of the invention,
13 the screw can cut threads in the pliable material
14 and this can help to hold the screw steady relative
15 to the bone fixture apparatus. Preferably the
16 pliable material is contained or received within the
17 hole that also accommodates the fixing device, and
18 the act of driving the fixing device through the
19 pliable material in the hole expands or deforms the
20 pliable material within the hole and holds the
21 fixing therein.

22
23 According to a further aspect of the present
24 invention, there is provided the use of a pliable
25 material in co-operation with a bone fixture
26 apparatus in a method of supporting a bone fracture.

27
28 According to a further aspect of the present
29 invention, there is provided a pliable insert for
30 engaging a fixing device for a bone fixture
31 apparatus.

32

1 According to a further aspect of the present
2 invention, there is provided a bone fixing apparatus
3 having at least one hole, wherein the hole is
4 provided with a tapered inner surface.
5

6 An embodiment of the invention will now be described
7 by way of example only and with reference to the
8 following drawings, in which:-
9

10 Fig 1 shows a cross-sectional view of an intra-
11 medullary nail inside the medullary canal of a
12 broken bone;

13 Fig 2 shows a side view of an intra-medullary
14 nail attached to a jig;

15 Fig 3 shows a cross-sectional view of an intra-
16 medullary nail filled with a pliable material;

17 Fig 4 shows a cross-sectional view of the
18 apparatus of Fig 3 with a screw extending
19 through the nail;

20 Fig 5 shows a cross-sectional view of an intra-
21 medullary nail on the interior of which is an
22 annulus of pliable material;

23 Fig 6 shows the cross-sectional view of the
24 apparatus of Fig 5 with a screw extending
25 through the nail;

26 Fig 7 shows a cross-sectional view through a
27 solid nail in accordance with another
28 embodiment;

29 Fig 8 shows a cross-sectional view through a
30 solid nail in accordance with a further
31 embodiment;

1 Fig 9 shows a cross-sectional view through a
2 tubular nail in accordance with another
3 embodiment;
4 Fig 10 shows a cross-sectional view through a
5 tubular nail in accordance with a further
6 embodiment;
7 Fig 11 is a front view of a bone plate
8 according to the invention;
9 Fig 12 is an enlarged view of one of the holes
10 in the bone plate of Fig 11;
11 Fig 13 is a cross-sectional view taken along
12 the line A-B of Fig 12;
13 Fig 14 is a cross-sectional view of the bone
14 plate of Fig 11 having a pliable insert;
15 Fig 15 is a cross-sectional view of the bone
16 plate of Fig 11 having an alternative
17 embodiment of insert;
18 Fig 16 shows a cross-sectional view of the Fig
19 14 bone plate and pliable insert, having a
20 screw driven through the insert; and
21 Figs 17 and 18 show cross-sectional views of a
22 further embodiment of bone plate and insert.
23
24 Referring now to the drawings, Fig 1 shows a bone
25 fixture apparatus in the form of an intra-medullary
26 nail 10, which is inserted inside the medullary
27 canal 12 of a broken bone 14. The broken bone 14
28 consists of two bone portions 16A and 16B. The
29 intra-medullary nail 10 extends substantially the
30 whole length of the medullary canal 12.
31

1 Fig 2 shows an intra-medullary nail 10 attached to a
2 jig 20 at one end. Both the nail 10 and the jig
3 have holes 18, 28 at each of their ends. Each hole
4 18 in the nail 10 is aligned with a respective hole
5 28 in the jig. A screw 26 is shown inserted through
6 a hole 18 in the nail 10, and a hole 28 in the jig
7 20.

8
9 One embodiment of the invention is illustrated in
10 Figs 3 and 4.

11
12 Fig 3 shows a hollow intra-medullary nail 10 of the
13 rolled tube type, which has lateral holes 18 aligned
14 at the same axial position on each side at the end
15 of the nail 10. The nail 10 is entirely filled with
16 a pliable material comprising a cylindrical insert
17 30 of polyethylene, which is inserted into the end
18 of the nail 10.

19
20 In use, the nail 10 is inserted into the medullary
21 canal of the bone portions 16A, 16B to be aligned.
22 The cylinder 30 of pliable material is inserted into
23 the nail 10 either before or after the nail 10 is
24 inserted into the medullary canal. The nail 10 is
25 then optionally attached at one end to a jig 20. At
26 least one screw 26 is driven into the bone on each
27 side of the break, at positions aligned with holes
28 in the jig 20 and holes 18 in the nail 10. The screws
29 26 pass through the holes 28 in the jig 20 and the
30 holes 18 in the nail 10, and engage the cylinder 30
31 of pliable material. The screw threads of screws 26
32 cut into the pliable material 30 as the screws are

1 driven into it, thereby ensuring a firm grip of the
2 screw by the cylinder 30. The pliable material of
3 the cylinder 30 is also displaced radially outwards
4 and expands against the inside surface of the nail
5 10, thereby pressing the cylinder 30 against the
6 nail 10. The increased grip between the screw 26
7 and the cylinder 30 and between the cylinder 30 and
8 the nail 10 helps to keep the screws 26 stationary
9 with respect to the nail 10, thereby preventing or
10 restraining movement of the nail in the bone 16
11 which can disrupt the healing process.

12

13 It should be understood that the use of the jig is
14 not essential for the working of this invention; it
15 is merely a useful tool to help to locate the holes
16 for the screws in alignment with the holes in the
17 nail 10.

18

19 Fig 4 shows the apparatus of Fig 3, with a screw 26
20 inserted through the holes 18 in the nail 10, and
21 through the cylinder 30. The pliable material of
22 the cylinder 30 has been squeezed outwards against
23 the inner surface of the nail 10 by the movement of
24 the screw 26, and exerts a force on the inside
25 surface of the nail 10 to keep the nail 10 in place.

26

27 An alternative embodiment of the invention is
28 described in Figs 5 and 6. This embodiment is
29 similar to that of Figs 3 and 4, except that the
30 pliable material is in the form of a liner or sleeve
31 32 that lines the inside surface of the nail 10 as

1 shown in Fig 5, instead of filling the entire cross-
2 section.

3
4 In use, the nail 10 is inserted into the medullary
5 canal as before. A hollow sleeve 32 of pliable
6 material is inserted into the nail 10 either before
7 or after the nail 10 is placed into the canal. The
8 nail 10 is then attached at one end to a jig 20. At
9 least one screw 26 is driven into the bone on each
10 side of the break at positions aligned with holes 28
11 in the jig 20 and holes 18 in the nail 10. Screws
12 26 are inserted through the hole 28 in the jig 20
13 and the hole 18 in the nail 10, and the screws 26
14 cut threads into the cylinder 32 of pliable
15 material, which helps to keep the screw 26 and the
16 intra-medullary nail 10 firmly connected with
17 reduced scope for movement of the nail 10 in the
18 bone during the healing process.

19
20 Fig 6 shows the embodiment of Fig 5 with a screw
21 inserted through the nail 10 and through the
22 cylinder 32 of pliable material.

23
24 The purpose of the pliable material is to hold the
25 screw in position and any shape/amount/type of
26 pliable material that achieves this function can be
27 used. It is generally useful if a part of the
28 pliable material forms, covers or surrounds a screw-
29 receiving hole in the intra-medullary nail so that
30 the screw self-taps into it, forming its own threads
31 or hole in the pliable material. It is advantageous
32 but not necessary for the pliable material to be

1 pressed against the nail, through either
2 displacement by the screw, and/or the pliable
3 material itself being self-expanding.

4
5 Figs 7 and 8 show how the invention can be applied
6 to a solid nail 50, which has a lateral bore 58 to
7 receive a screw. The bore 58 is lined with a sleeve
8 52 in the fig 7 embodiment that is formed from
9 pliable material (in this case the pliable material
10 is a polyamide). The sleeve 52 is deformed by the
11 screw threads as the screw penetrates the bore, and
12 this enhances the grip between the nail and the
13 screw. The sleeve 52 can be replaced by one or more
14 annular rings 54 that can usefully be positioned at
15 opposite ends of the bore 58 as shown in the Fig 8
16 embodiment.

17
18 The annular rings 54 or the sleeve 52 can be used in
19 a tubular nail 10 as shown in Fig 9 and Fig 10.
20 It is not important which particular pliable
21 material is used; suitable materials include metals,
22 polymers (absorbable/non-absorbable), non-metallic
23 materials (e.g. carbon complexes) and naturally
24 occurring materials (e.g. collagen constructs).

25
26 It could be advantageous for the patient if only
27 small quantities of pliable material are used, so as
28 to keep the amount of foreign agents in his body to
29 a minimum. Typically pliable materials that are
30 biodegradable are preferred.

31

1 A further alternative embodiment of the invention is
2 shown in Figs 11 to 14. Fig 11 shows a bone plate
3 60 which has a series of oval holes 62 and circular
4 holes 64 along its length; each hole extends through
5 the plate from an upper surface 66 of the plate to a
6 lower surface 68. One of the circular holes 64' is
7 shown in more detail in Figs 12 and 13.

8
9 As best seen in Fig 13, the hole 64' has walls 65
10 which are tapered so that they are inclined relative
11 to each other and to the upper and lower surfaces
12 66, 68 of the bone plate. The hole 64' also has a
13 central axis X.

14
15 The wall 65 of the hole 64' inclines radially
16 inwardly towards the hole axis X from the top
17 surface 66 to an apex 70, from where the wall 65
18 inclines radially outwards to the lower surface 68.
19 The apex 70 is located slightly below the midpoint
20 of the hole 64'. The cross-section of the hole 64'
21 thus generally resembles an hourglass.

22
23 Referring now to Fig 14, a pliable insert 72 also
24 having the form of an hourglass is shown inserted
25 into the hole 64'. The pliable insert 72 is formed
26 so that it fits inside the hole in a clearance fit.
27 Ideally, once inserted there should be essentially
28 no gap between the insert 72 and the wall 65 of the
29 bone plate 60.

30
31 The pliable insert 72 can typically be squeezed into
32 the hole 64'. For example, the material of the

1 pliable insert 72 could be chosen such that a slight
2 heating of the pliable insert 72 would make the
3 insert 72 compressible to fit in the hole 64'.

4 Other embodiments can be envisaged where the pliable
5 insert 72 is formed in the hole 64' by melting the
6 pliable material and allowing it to set within the
7 hole.

8
9 Once inserted, the insert 72 is retained in the hole
10 64' by the hourglass-shape of the walls 65. The
11 insert 72 would typically be inserted into the hole
12 64' before surgery, but in certain circumstances the
13 insert 72 can be inserted peroperatively.

14
15 The interior surfaces of the other holes 62, 64 in
16 the bone plate 60 have a similar shape.

17
18 Fig 15 shows the hole 64' of the bone plate 60
19 having an alternative embodiment of pliable insert
20 76, typically made from a resilient material such as
21 a resilient plastics material or a rubber. The
22 lower end 78 (defined with reference to the bone
23 plate) of the insert 76 has wedge-shaped slits 80
24 cut between adjacent legs. The slits 80 are aligned
25 parallel to the axis X, with the tip of each cut-out
26 wedge at the upper end of each slit 80, giving a
27 pleated effect. The legs of the insert 76 do not
28 extend all of the way to the lower surface 68 of the
29 plate 60 in this embodiment. The upper end 77 of
30 the insert 76 mirrors the shape of the upper parts
31 of the walls 65.

32

1 The insert 76 is engaged in the hole by squeezing
2 the legs at the lower end 78 of the insert 76 so
3 that the slits 80 are compressed together, the legs
4 are parallel to one another, and the lower end 78 of
5 the insert 76 is squeezed into a generally
6 cylindrical arrangement that can pass the apex 70 of
7 the walls 65. Thus, the insert 76 can be squeezed
8 into the hole 64' and once in position, the
9 resilience of the pliable insert 76 will cause the
10 slits 80 to assume their original wedge-like shapes,
11 splaying the legs outwards, and the lower end of the
12 insert 76 will be trapped below the apex 70, thus
13 retaining the insert 76 in the hole 64', as shown in
14 Fig 15.

15

16 This embodiment provides the advantage that the
17 insert 76 can be inserted into the hole 64' without
18 any external heating or special application of extra
19 force, so the insert 76 can easily be inserted into
20 any suitable hole at any time before or during the
21 operation with an easy press-fit. Driving a fixing
22 device such as a screw through the insert 76 will
23 keep the legs splayed and securely anchor the insert
24 76 within the hole 64'.

25

26 Fig 16 shows the bone plate 60 and insert 72 of Fig
27 14, with a screw 82 screwed into the insert 72. The
28 screw 82 has a head 84 and a shaft 86, both of which
29 are threaded. The screw 82 is inserted far enough
30 into the insert 72 such that the head 84 is threaded
31 into the insert 72 in addition to the shaft 86. The
32 threads of the screw 82 cut into the bone (not

1 shown) and the screw 82 acts as a fixing device to
2 attach the bone plate 60 to the bone.

3

4 The axis of the screw 82 is shown by the line Y in
5 Fig 16; it is not co-axial with the axis X of the
6 hole 64' but is inclined relative thereto. The
7 invention provides the significant advantage over
8 conventional bone fixing devices that it allows the
9 selection of the angle of insertion of the screw 82,
10 without the surgeon being forced to change the
11 attitude or orientation of the hole or the bone
12 plate 60. Examples of several possible screw
13 orientations are shown as dotted lines S, T, U, V in
14 Figs 14 and 15. The screw position/angle is
15 typically chosen prior to the insertion of the screw
16 82. The angle of screw insertion would typically be
17 influenced by the diameter of the leading thread of
18 screw, the core diameter of the screw, and the shape
19 and diameter of the screw head.

20

21 The insert 76 of the Fig 15 embodiment can receive a
22 screw in just the same way as shown in Fig 16 for
23 the insert 72.

24

25 The inserts 72, 76 could either be formed with one
26 or more predrilled holes for insertion of screws, or
27 alternatively, the inserts 72, 76 could be solid and
28 the screw holes could be drilled according to the
29 surgeon's requirements or judgement during the
30 operation. An advantage of pre-drilled holes is
31 that this eliminates the possibility that the
32 surgeon might drill through the insert and into the

1 bone plate. On the other hand, if a hole is drilled
2 in a solid insert during the operation, the surgeon
3 has complete freedom of choice of hole angle.

4
5 The embodiments described in Figs 14 to 16 are
6 adapted for circular holes and have axial symmetry,
7 so that the inserts 72, 76 can be rotated in their
8 respective holes. Rotation of the insert 72, 76
9 sweeps the angle of the hole around in an arc,
10 allowing the surgeon even more freedom of choice to
11 insert the screw 82 at the required angle, or in the
12 required direction.

13
14 Fig 17 shows a yet further alternative embodiment,
15 wherein a bone plate 90 has an upper surface 92 and
16 a lower surface 94. The bone plate 90 has holes 96
17 (only one shown) having tapered walls. The hole 96
18 is frusto-conical, the narrower end being at the
19 lower surface 94 and the wider end being at the
20 upper surface 92. Thus, the walls of the hole 96
21 are inclined radially inwards from the upper surface
22 92 to the lower surface 94. Unlike the embodiments
23 of Figs 11 to 16, there is no apex in the surface of
24 the walls, the inclination being typically
25 continuous between the upper and lower surfaces 92,
26 94, although an annular stop could be formed at the
27 lower surface 94 if desired (not shown).

28
29 The hole 96 has a pliable insert 98 inserted
30 therein. The insert 98 is also in the form of a
31 trapezium, being dimensioned to fit the shape of the
32 hole 96, so that the insert 98 fits in and fills the

1 hole 96 as shown in Fig 17. The angle of
2 inclination of the sides is exaggerated in figure
3 17, and in practice any significant inclination of
4 the walls is useful, as it permits the insert to
5 enter and leave the hole only through the wider
6 aperture of the top surface 92.

7
8 In certain simple embodiments of this version, the
9 sidewalls (i.e. not the upper and lower surfaces) of
10 both of the insert 98 (typically) and the hole 96
11 can be plain, but in the more advanced embodiment
12 shown the sidewall of at least the hole 96 is screw
13 threaded in order to grip the insert 98 more
14 securely. The outer wall of the insert can also be
15 threaded as shown in this embodiment, but in other
16 versions, it is sufficient for the thread to be cut
17 into the insert 98 by the thread on the hole 96
18 during insertion of the insert 98 into the hole 96.
19 In this example, the coupled threads are designated
20 100 in the drawing. Therefore, this embodiment
21 provides a pliable insert that can be screwed into a
22 bone plate by engaging the threads of the plate
23 aperture and the insert. The insert 98 can be
24 screwed into holes in conventional bone plates where
25 required in order to fix the insert more securely to
26 the plate. Thus, when the screw or other bone
27 fixing device is driven through the insert 98, the
28 consequent deformation of the insert 98 pushes the
29 plastic of the insert even more firmly into the
30 threads on the inner surface of the hole 96, thereby
31 reducing the possibility of the insert allowing any

1 play of the plate and fixing after the two are
2 finally connected.

3

4 As with previous embodiments, the screws or other
5 fixings can be driven through the solid plug of the
6 insert 98 or alternatively the insert 98 can have
7 pre-drilled holes to guide insertion of the fixings.
8 Naturally, with pre-drilled holes in the insert 98,
9 the insert 98 can be rotated to select a suitable
10 path for the fixing into the bone. This feature
11 can be especially useful if part of the bone is
12 comminuted, the bone portions in these parts being
13 very tiny, and where especially accurate selection
14 of the angle of insertion of the screws is required.
15 In some embodiments, some of the holes in the bone
16 plate could be used with screws directly, and the
17 holes relating to the comminuted parts of the
18 fracture could be filled with an insert according to
19 the invention.

20

21 Fig 18 shows the Fig 17 insert 98 with a screw 82
22 driven therethrough.

23

24 The invention allows the use of smaller screws, as
25 in this invention, the size of the screw is not
26 defined by the size of the hole in the bone plate;
27 any size of screw smaller than the hole can be
28 chosen. Again, this may be particularly useful for
29 comminuted fractures.

30

31 If the conventional bone plate has holes with
32 parallel walls, a correspondingly parallel-walled

1 insert could be provided. Therefore, this invention
2 also provides embodiments which can be used in
3 conjunction with conventional bone plates/
4 intramedullary nails, as and where required, to give
5 the advantage of being able to select the angle of
6 insertion of the hole and the required screw size.

7
8 It should be noted that the non-parallel sided
9 designs of insert and bone fixture apparatus in the
10 embodiments of Figs 11 to 17 could equally be
11 applied to the intra-medullary nail embodiments;
12 these do not necessarily relate only to bone plates.

13
14 It should also be noted that in the embodiments of
15 Fig 17 and 18 it is not necessary for the insert 98
16 to be threaded, and the thread can be cut into the
17 insert 98 by the act of screwing a blank insert 98
18 into the hole.

19
20 Modifications and improvements can be incorporated
21 without departing from the scope of the invention.
22 For example, the bone fixture apparatus may be a
23 bone plate, a fracture brace or any other kind of
24 bone fixture apparatus; the invention does not
25 necessarily relate to intra-medullary nails.

26
27 Other types of pliable material may be used beyond
28 the types specifically mentioned above.

29
30 The bone fixture apparatus does not necessarily
31 include holes. For example, the pliable material
32 could be bonded to the bone fixture apparatus and a

1 fixing device could be engaged with the pliable
2 material alone.
3

1 Claims

2

3 1. A bone fixture apparatus having a pliable
4 material for engaging a fixing device.

5

6 2. A bone fixture apparatus as claimed in claim 1,
7 wherein the pliable material is deformable.

8

9 3. A bone fixture apparatus as claimed in claim 1
10 or claim 2, wherein the pliable material comprises
11 an insert.

12

13 4. A bone fixture apparatus as claimed in any
14 preceding claim, wherein the form of the pliable
15 material is selected from the group consisting of a
16 hollow sleeve, at least one ring, a plug, a coating
17 and a liner.

18

19 5. A bone fixture apparatus as claimed in any
20 preceding claim, wherein the pliable material is
21 received in a threaded aperture in the apparatus.

22

23 6. A bone fixture apparatus as claimed in any
24 preceding claim, wherein the pliable material is
25 settable.

26

27 7. A bone fixture apparatus as claimed in any
28 preceding claim, wherein the pliable material is
29 expandable.

30

31 8. A bone fixture apparatus as claimed in claim 7,
32 wherein the pliable material is self-expanding.

1

2 9. A bone fixture apparatus as claimed in any
3 preceding claim, wherein the pliable material lines
4 at least a part of the inside of the bone fixture
5 apparatus.

6

7 10. A bone fixture apparatus as claimed in any
8 preceding claim, wherein the pliable material is
9 located within a passage of the bone fixture
10 apparatus.

11

12 11. A bone fixture apparatus as claimed in claim
13 10, wherein the pliable material fills the
14 transverse cross-sectional area of the passage.

15

16 12. A bone fixture apparatus as claimed in any
17 preceding claim, wherein the bone fixture apparatus
18 has at least one hole to receive a respective fixing
19 device and wherein the pliable material is located
20 in a region of the hole.

21

22 13. A bone fixture apparatus as claimed in claim
23 12, wherein the pliable material lines the inside of
24 the hole.

25

26 14. A bone fixture apparatus as claimed in claim 12
27 or claim 13, having a cylindrical passage through
28 the bone fixture apparatus terminating in a
29 respective hole at each end of the passage.

30

31 15. A bone fixture apparatus as claimed in claim
32 14, wherein the pliable material is located at each

1 end of the passage, around the inside surface of the
2 passage.

3

4 16. A bone fixture apparatus as claimed in claim 14
5 or claim 15, wherein the entire passage is filled
6 with pliable material.

7

8 17. A bone fixture apparatus as claimed in claim 12
9 or claim 13, wherein the bone fixture apparatus is
10 hollow and the pliable material is in the form of a
11 sleeve or cylinder that spans the gap between holes
12 in opposite sides of the bone fixture apparatus.

13

14 18. A bone fixture apparatus as claimed in any of
15 claims 12 to 17, wherein the hole is tapered.

16

17 19. A bone fixture apparatus as claimed in any of
18 claims 12 to 18, wherein the pliable material is in
19 the form of an insert which fills the hole.

20

21 20. A bone fixture apparatus as claimed in claim
22 19 when dependent on claim 18, wherein the insert
23 tapers to match the shape of the hole.

24

25 21. A bone fixture apparatus as claimed in claim 19
26 or claim 20, wherein the hole and the insert are
27 frusto-conical.

28

29 22. A bone fixture apparatus as claimed in any of
30 claims 19 to 21, wherein the insert has a
31 compressible portion, which can be compressed to fit
32 through a narrow section of the hole.

1

2 23. A bone fixture apparatus as claimed in claim
3 22, wherein the compressible portion has slits.

4

5 24. A bone fixture apparatus as claimed in claim 22
6 or claim 23, wherein the compressible portion is
7 adapted to splay outwards to retain the insert in
8 the hole after insertion.

9

10 25. A bone fixture apparatus as claimed in any of
11 claims 19 to 24, wherein the insert is rotatable in
12 the hole.

13

14 26. A bone fixture apparatus as claimed in any of
15 claims 19 to 25, wherein the hole is provided with
16 internal screw threads.

17

18 27. A bone fixture apparatus as claimed in claim
19 26, wherein the insert has external screw threads to
20 engage the internal threads on the hole, such that
21 the insert can be screwed into the hole.

22

23 28. A bone fixture apparatus as claimed in any of
24 claims 19 to 27, wherein the insert has an aperture
25 therethrough to receive a fixing device.

26

27 29. A bone fixture apparatus as claimed in any
28 preceding claim, wherein the pliable material is
29 contained within a containment area of the bone
30 fixture apparatus.

31

1 30. A bone fixture apparatus as claimed in any
2 preceding claim, wherein the pliable material is
3 fixed to the bone fixture apparatus.

4
5 31. A bone fixture apparatus as claimed in any
6 preceding claim, wherein the pliable material is
7 selected from the group consisting of metals and
8 polymers.

9
10 32. A bone fixture apparatus as claimed in any
11 preceding claim, wherein the pliable material is
12 selected from the group consisting of a plastics
13 material, a carbon complex, polyethylene, nylon, and
14 collagen and polypeptide constructs.

15
16 33. A bone fixture apparatus as claimed in any
17 preceding claim, wherein the pliable material is
18 biodegradable or bioabsorbable.

19
20 34. A bone fixture apparatus as claimed in any
21 preceding claim, wherein the bone fixture apparatus
22 comprises an intra-medullary nail.

23
24 35. A bone fixture apparatus as claimed in any of
25 claims 1 to 33, wherein the bone fixture apparatus
26 comprises a bone plate.

27
28 36. A method of supporting a fractured bone, the
29 method comprising the steps of: attaching a bone
30 fixture apparatus to the bone and engaging at least
31 one fixing device with the bone, wherein the bone
32 fixture apparatus is provided with a pliable

1 material and the fixing device is engaged with the
2 pliable material.

3

4 37. A method as claimed in claim 36, wherein the
5 fixing device is threaded, and wherein on insertion,
6 the fixing device cuts threads in the pliable
7 material to hold the fixing device relative to the
8 pliable material.

9

10 38. A method as claimed in claim 36 or claim 37,
11 wherein the insertion of the fixing device displaces
12 some of the pliable material against the inside
13 surface of the bone fixture apparatus.

14

15 39. A method as claimed in any of claims 36 to 38,
16 wherein the pliable material is expandable upon
17 application of pressure and the insertion of the
18 fixing device causes the pliable material to expand.

19

20 40. A method as claimed in any of claims 36 to 39,
21 wherein the pliable material is contained within a
22 containment area in the bone fixture apparatus, and
23 when the fixing device is inserted, the pliable
24 material is displaced against the walls of the
25 containment area.

26

27 41. A method as claimed in any of claims 36 to 40,
28 wherein the fixing device is inserted through the
29 bone and through at least one hole in the bone
30 fixture apparatus.

31

1 42. A method as claimed in claim 41, wherein the
2 pliable material lines the hole in the bone fixture
3 apparatus.

4
5 43. A method as claimed in claim 41 or claim 42,
6 wherein the pliable material is in the form of an
7 insert which fills the hole in the bone fixture
8 apparatus.

9
10 44. A method as claimed in claim 43, wherein the
11 hole has internal threads, and the method includes
12 the step of screwing the insert into the hole.

13
14 45. A method as claimed in claim 44, wherein the
15 insert has external threads that engage with the
16 threads on the hole.

17
18 46. A method as claimed in any of claims 43 to 45,
19 wherein the insert is solid and an aperture is
20 drilled in the insert during surgery.

21
22 47. A method as claimed in any of claims 43 to 45,
23 wherein the insert has a predrilled aperture, which,
24 in use, is inclined relative to the hole axis, and
25 the method includes the step of rotating the insert
26 to select the orientation of the aperture.

27
28 48. A method as claimed in any of claims 43 to 47,
29 wherein the hole has an internal throat and the
30 insert has a compressible portion, and the method
31 includes the step of compressing the portion to fit

1 the insert at least partially through the throat of
2 the hole.

3

4 49. A method as claimed in claim 48, wherein the
5 compressible portion has legs which can be pushed
6 together to compress the portion to fit the insert
7 through the throat of the hole and which splay apart
8 when in position in the hole to grip the hole.

9

10 50. The use of a pliable material in co-operation
11 with a bone fixture apparatus in a method of
12 supporting a bone fracture.

13

14 51. A pliable insert for engaging a fixing device
15 for a bone fixture apparatus.

16

17 52. A pliable insert as claimed in claim 51,
18 wherein the insert is deformable.

19

20 53. A pliable insert as claimed in claim 51 or
21 claim 52, wherein the insert has external screw
22 threads.

23

24 54. A pliable insert as claimed in any of claims 51
25 to 53, wherein the insert is settable.

26

27 55. A pliable insert as claimed in any of claims 51
28 to 54, wherein the insert is expandable.

29

30 56. A pliable insert as claimed in claim 55,
31 wherein the insert is self-expanding.

32

1 57. A pliable insert as claimed in any of claims 50
2 to 56, wherein the insert tapers bi-directionally to
3 form a waist.

4

5 58. A pliable insert as claimed in any of claims 51
6 to 57, wherein the insert has a compressible end.

7

8 59. A pliable insert as claimed in claim 58,
9 wherein the compressible end has legs divided by
10 slits, and wherein the legs can be pushed together
11 to compress the end.

12

13 60. A pliable insert as claimed in claim 59,
14 wherein the legs of the insert are adapted to splay
15 outwards on the engagement of a fixing device with
16 the insert.

17

18 61. A bone fixture apparatus as claimed in any of
19 claims 51 to 60, wherein the insert has an aperture
20 therethrough to receive a fixing device.

21

22 62. A pliable insert as claimed in any of claims 51
23 to 61, wherein the insert comprises a material
24 selected from the group consisting of metals and
25 polymers.

26

27 63. A pliable insert as claimed in any of claims 51
28 to 62, wherein the insert comprises a material
29 selected from the group consisting of a plastics
30 material, a carbon complex, polyethylene, nylon, and
31 collagen and polypeptide constructs.

32

1 64. A pliable insert as claimed in any of claims 51
2 to 63, wherein the insert is biodegradable.

3

4 65. A bone fixing apparatus having at least one
5 hole, wherein the hole is provided with a tapered
6 inner surface.

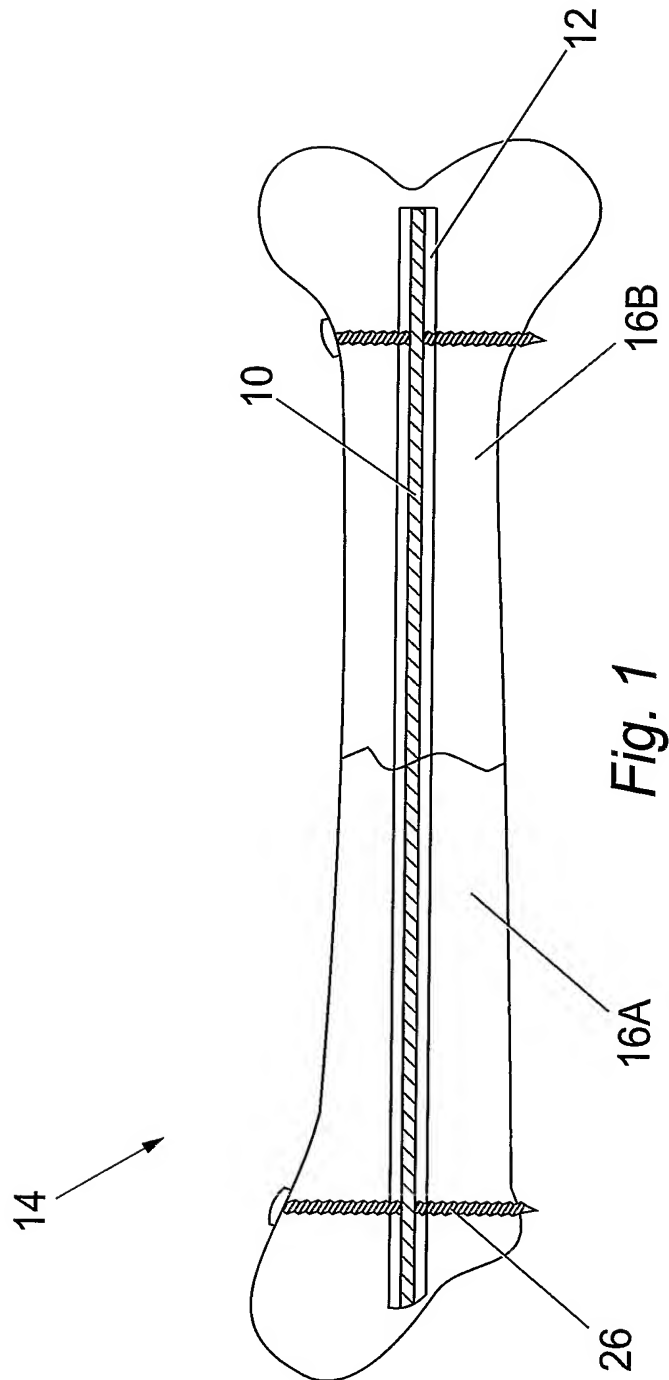
7

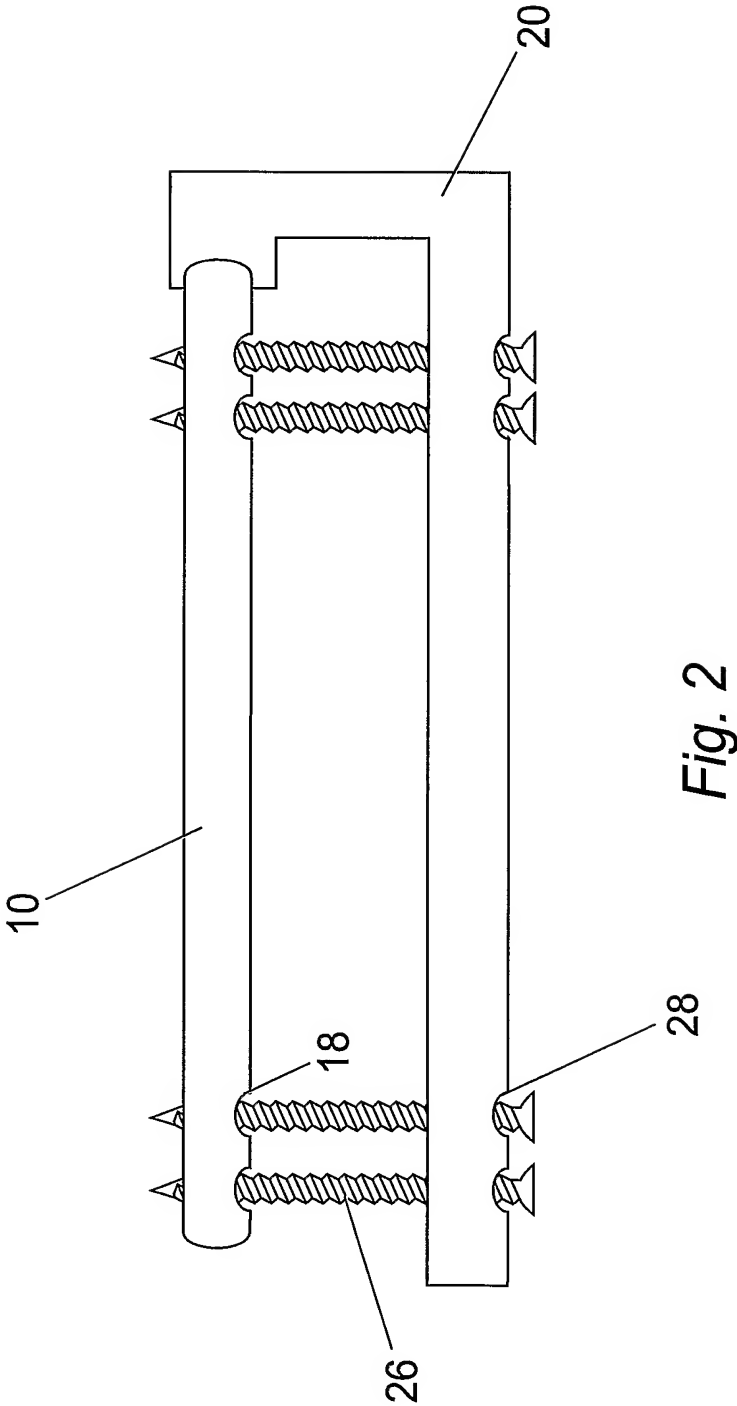
8 66. A bone fixing apparatus as claimed in claim 65,
9 wherein the hole is bi-directionally tapered to form
10 a throat.

11

12

1 / 13





3 / 13

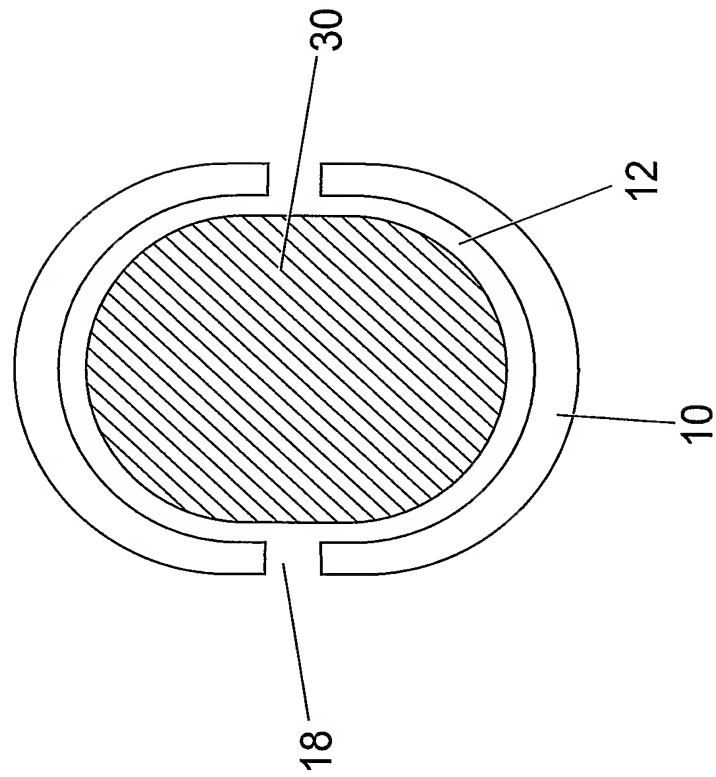


Fig. 3

4 / 13

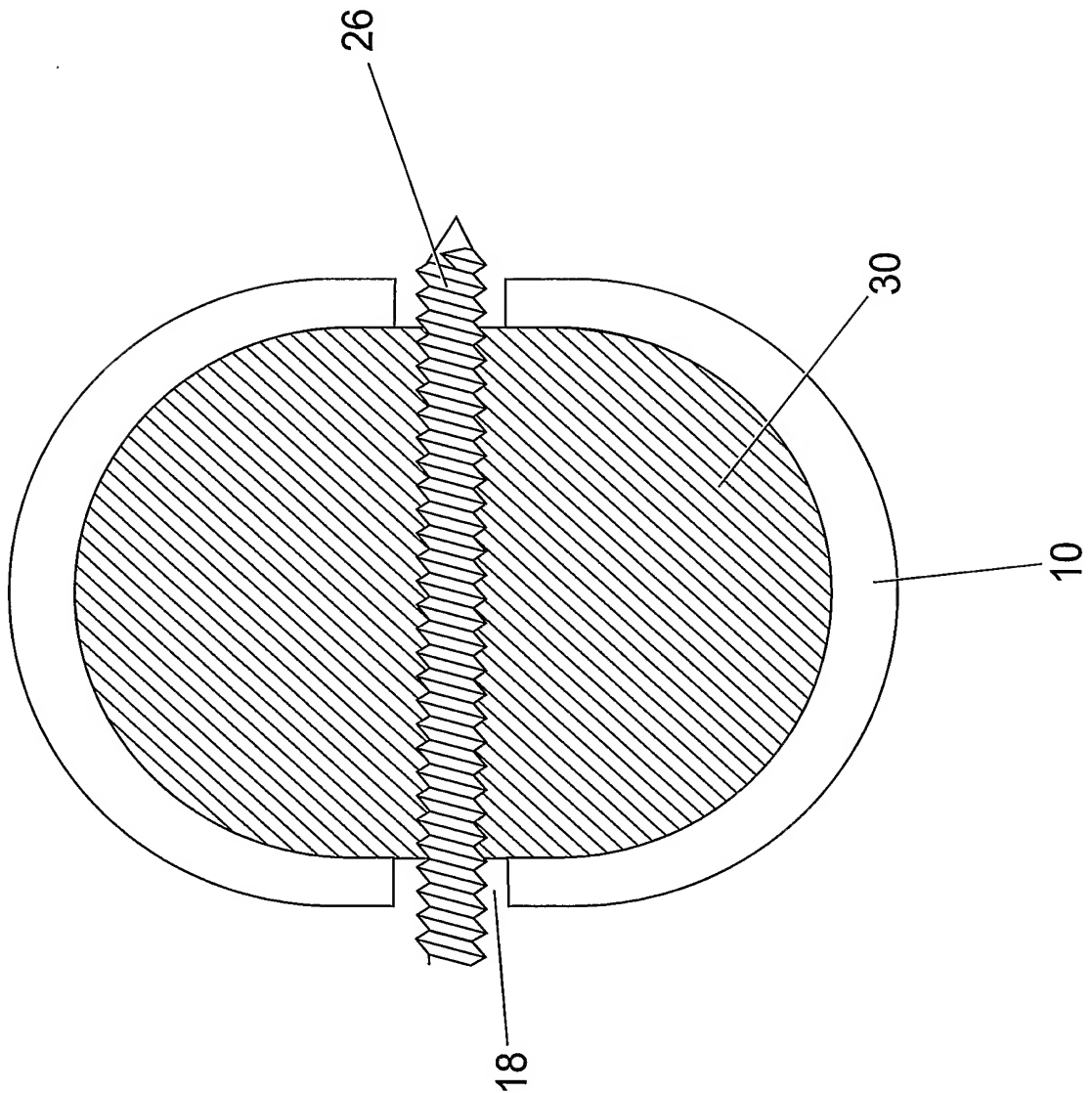


Fig. 4

5 / 13

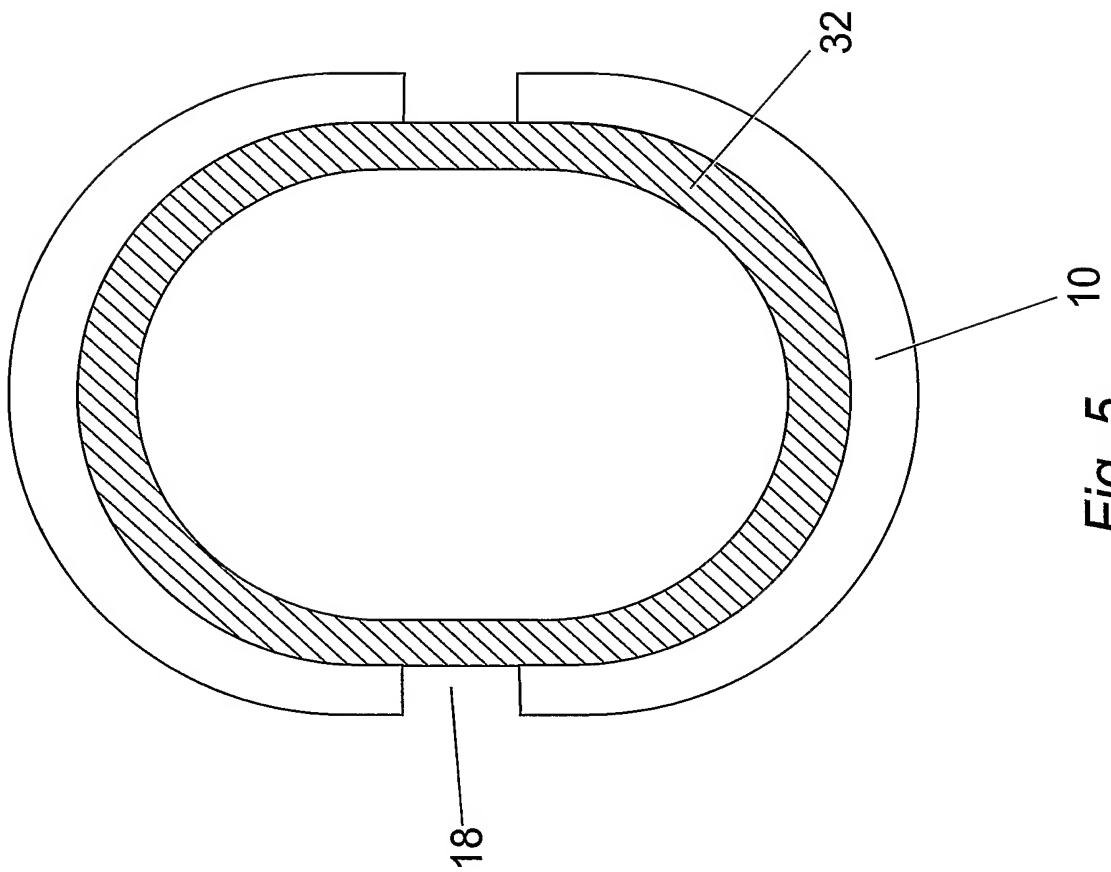


Fig. 5

6 / 13

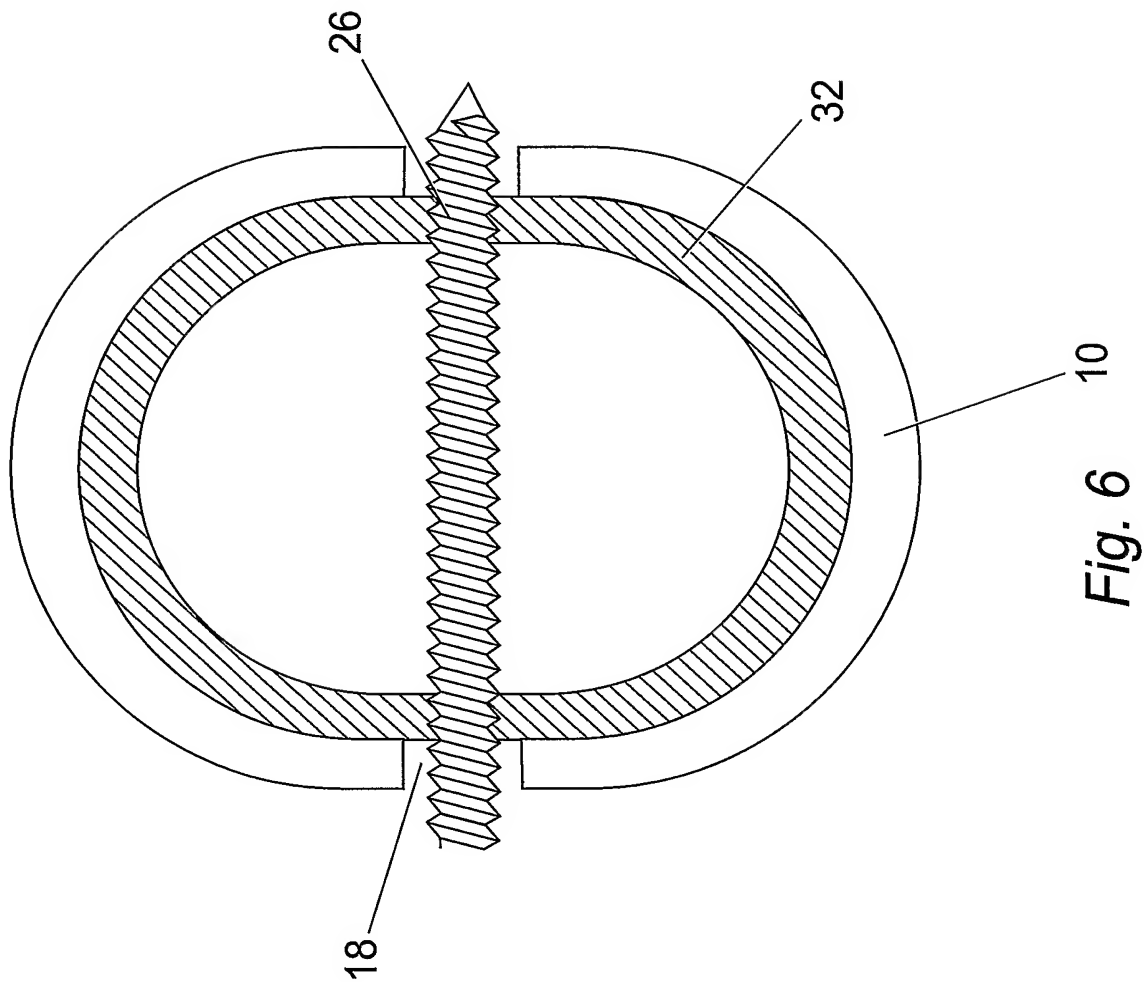


Fig. 6

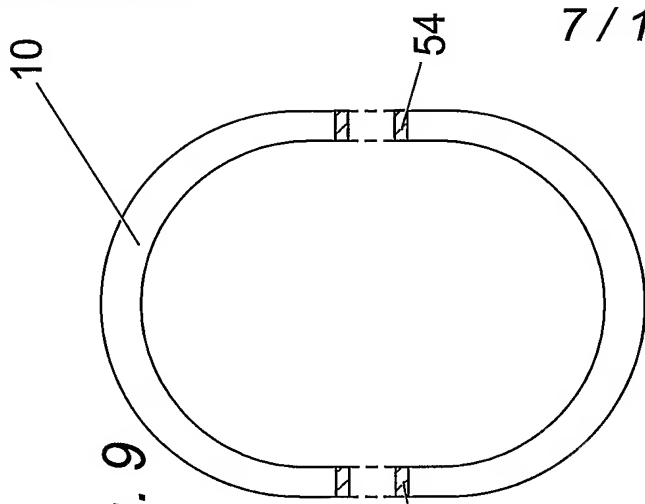


Fig. 9

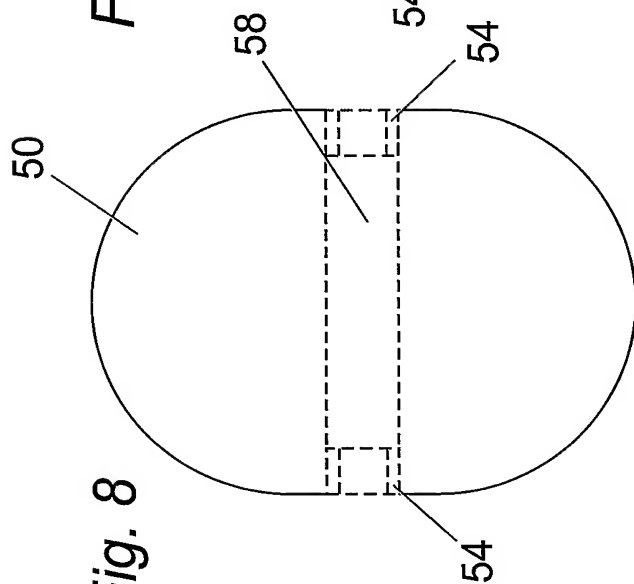


Fig. 8

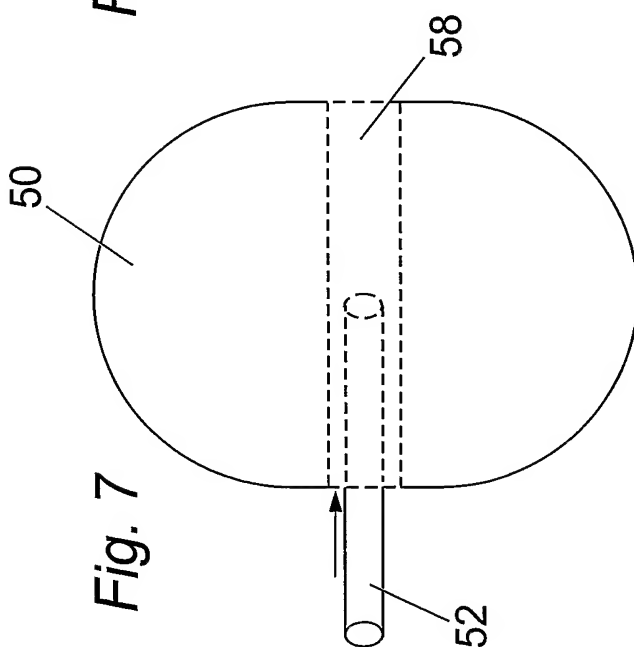


Fig. 7

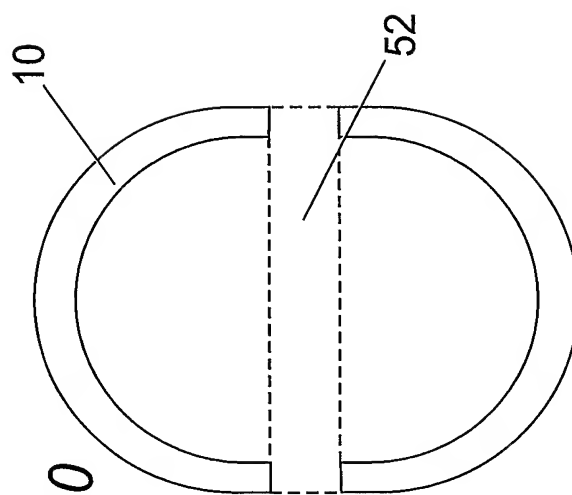


Fig. 10

8 / 13

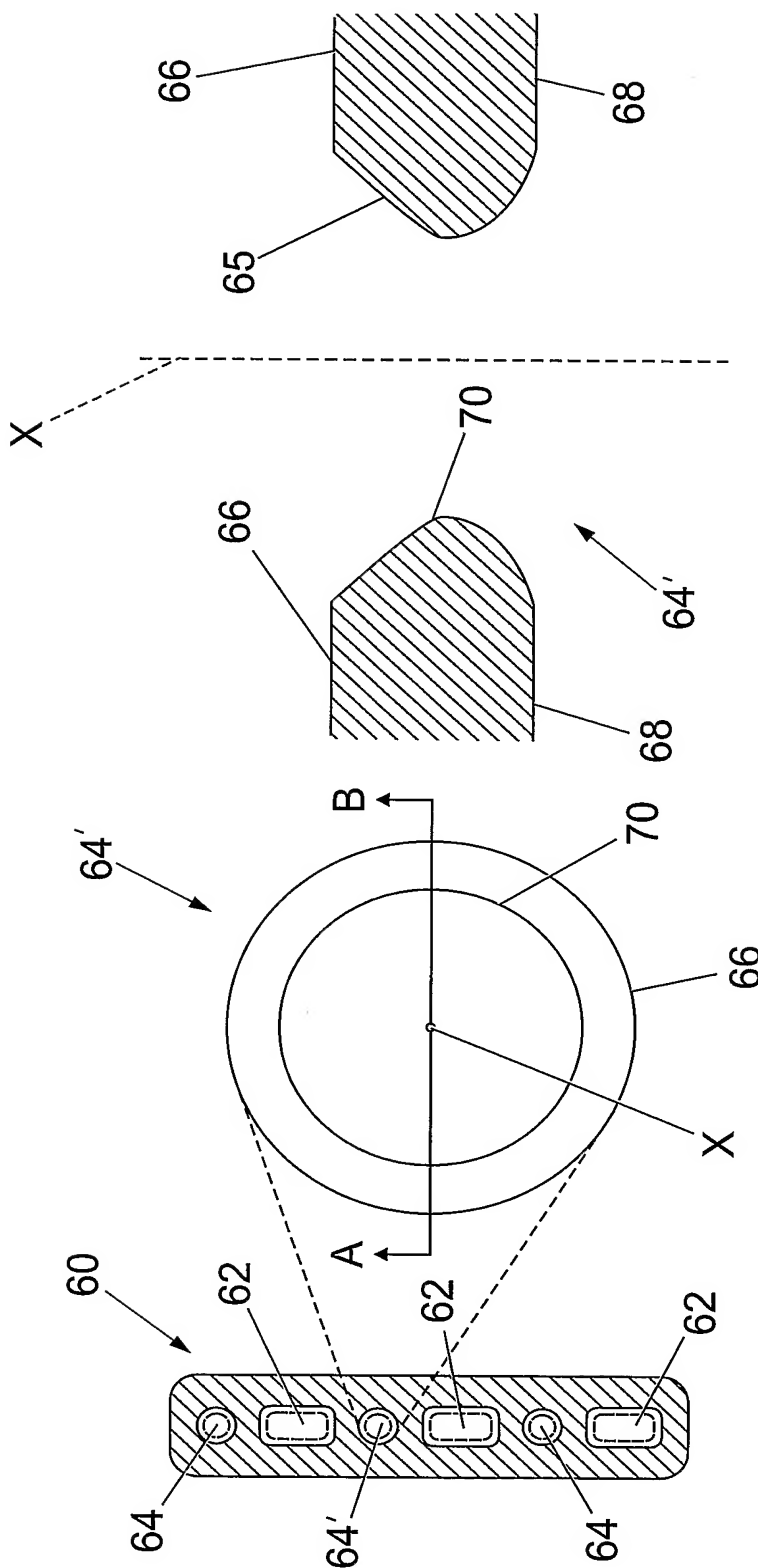
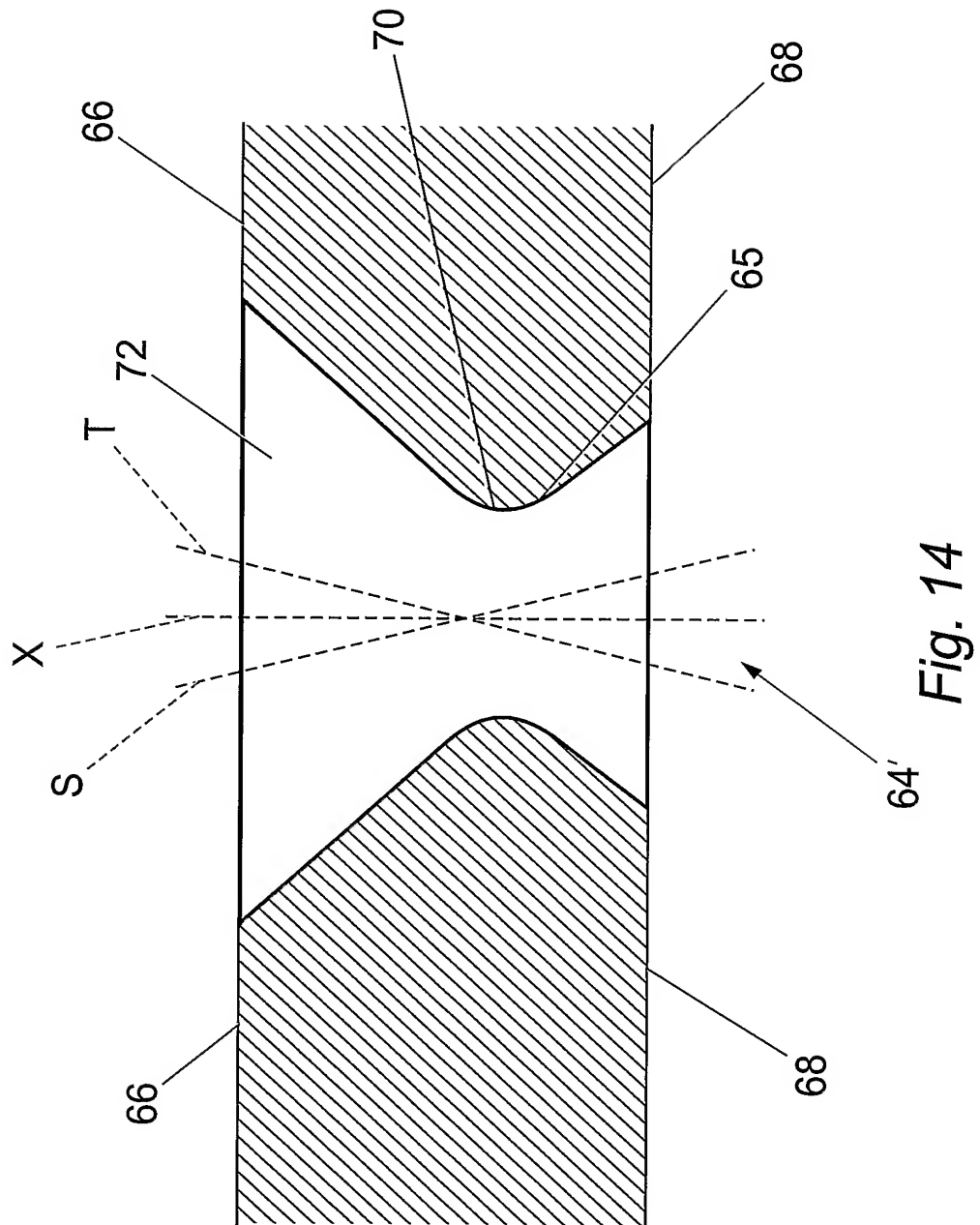


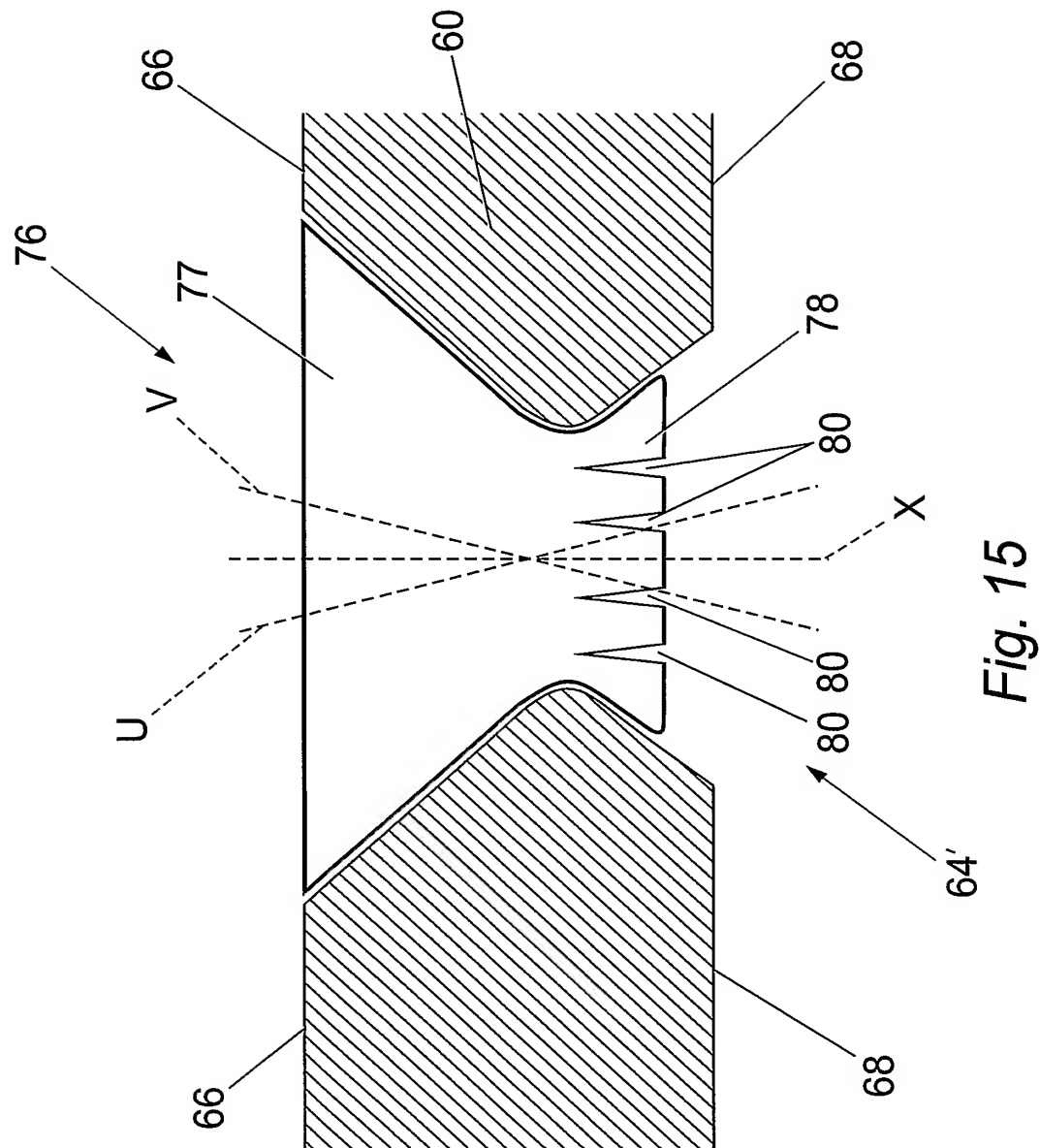
Fig. 13

Fig. 12

Fig. 11

9 / 13





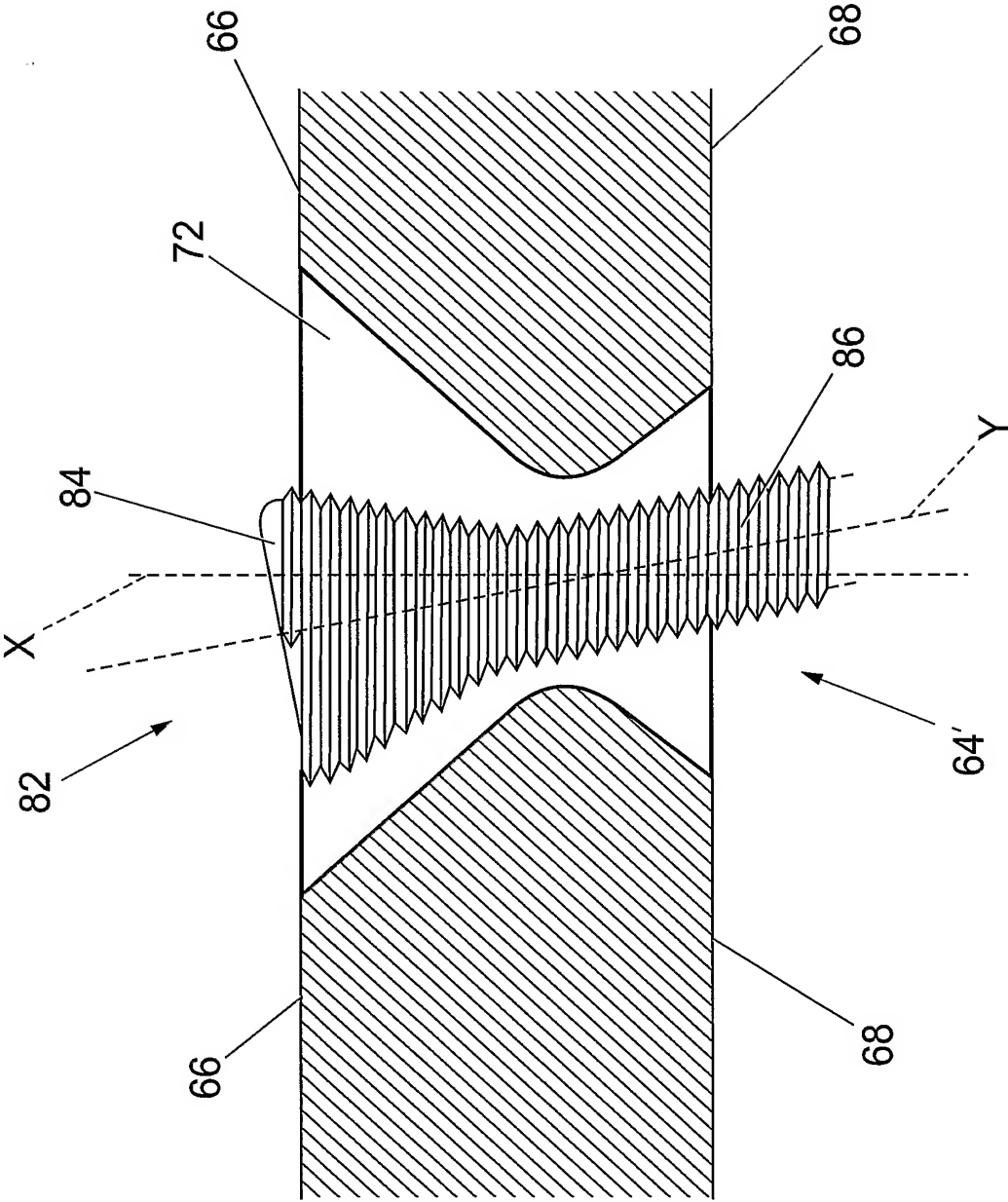


Fig. 16

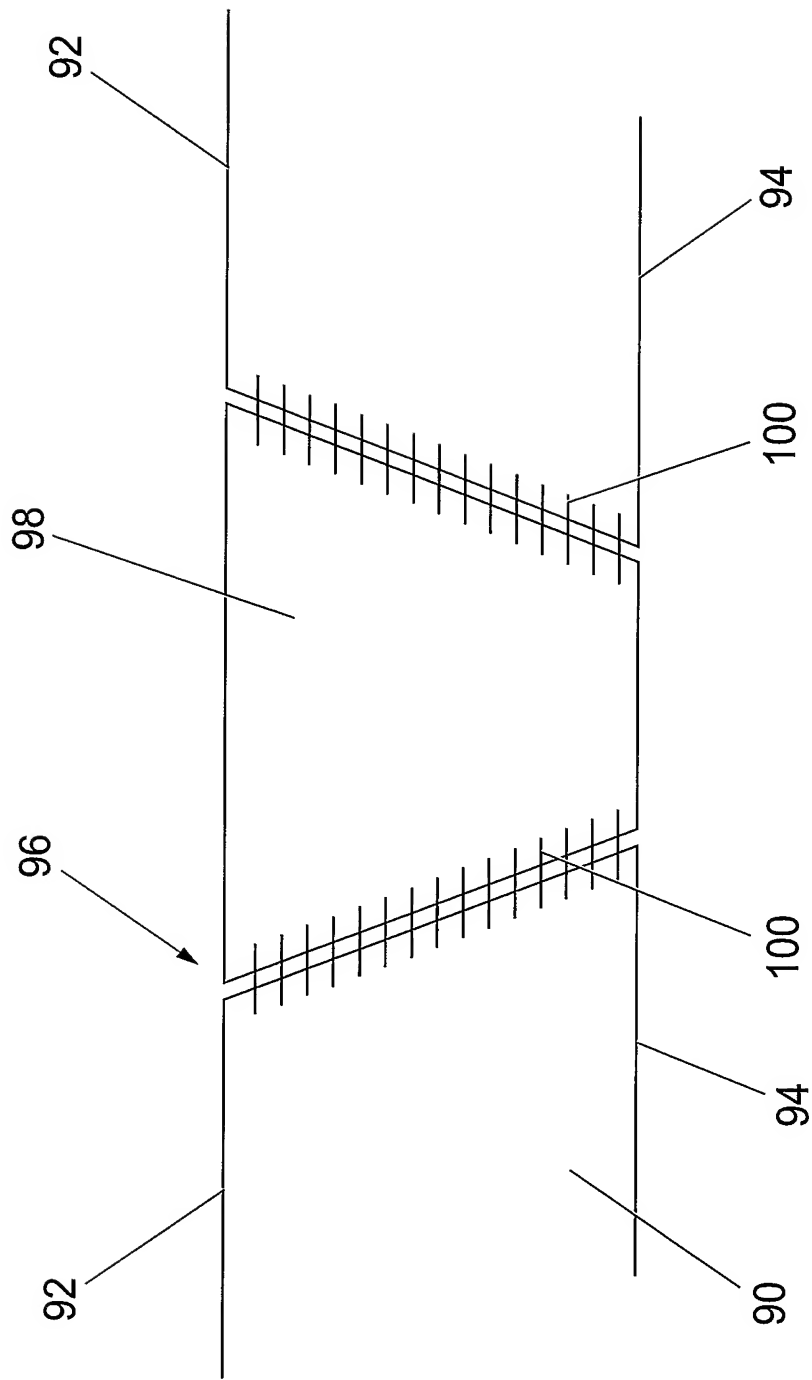


Fig. 17

13 / 13

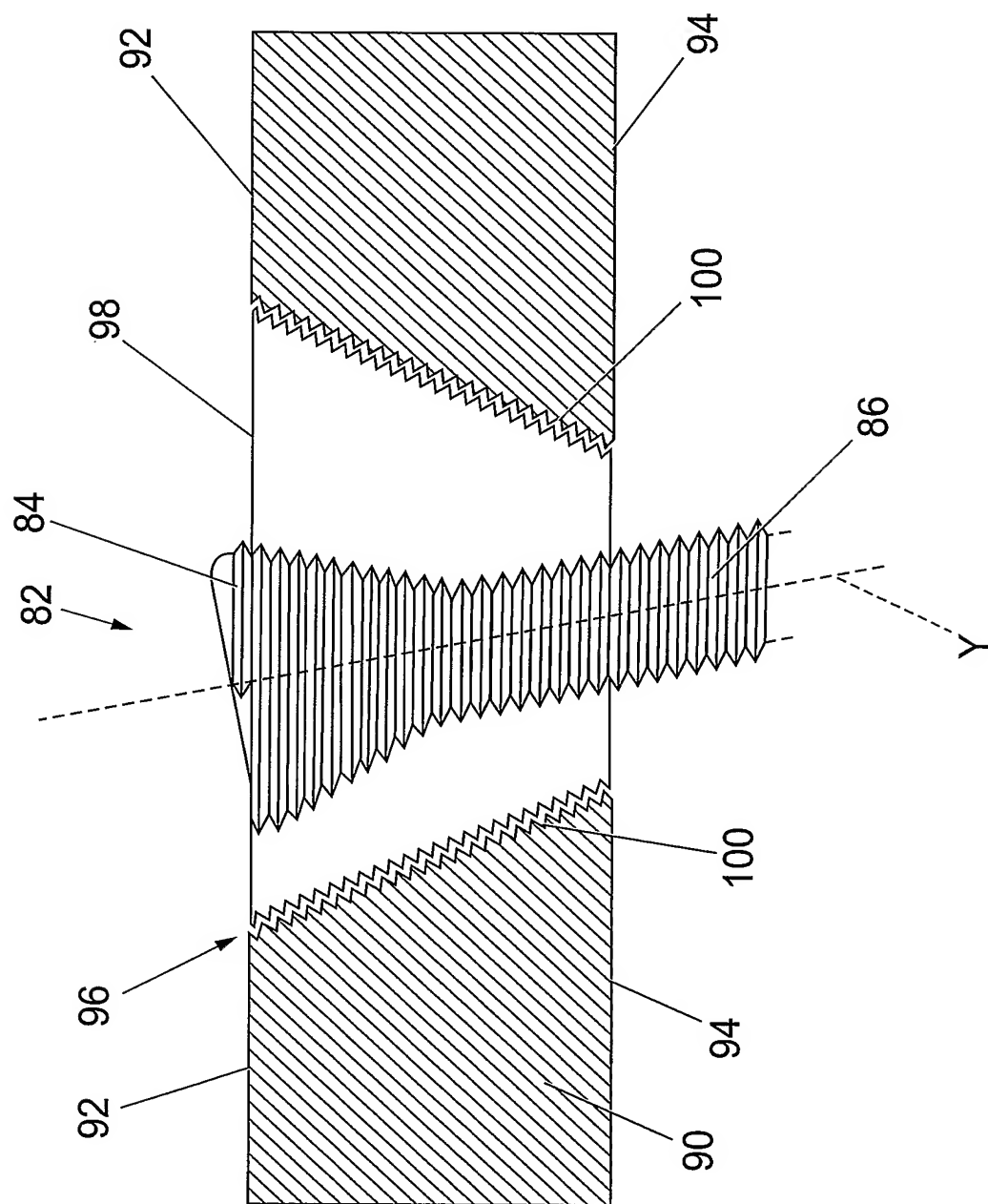


Fig. 18